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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,003	01/09/2001	Vijay R. Baichwal	T95-006-2	8531

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EXAMINER

ANDRES, JANET L

ART UNIT PAPER NUMBER

1646

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/758,003

Applicant(s)

BAICHWAL ET AL.

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-3,5,6 and 10-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,10-27 and 29-34 is/are rejected.
- 7) ☒ Claim(s) 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

1. Applicant's species election of $\alpha\Delta 14$ is acknowledged. The requirement is withdrawn because separate searches were not required. Claims 1-3, 5, 6, and 10-34 are pending and under examination in this application.

Specification

2. The title is objected to because of the use of the word "novel". Novelty is a legal concept and does not describe the invention claimed. Novelty is required of all claimed inventions before they are issued as patents. To use the term in the title would imply merit in this regard without actual examination. Accordingly, though MPEP 606.01 does not specifically refer to "novel", it is similar to the term "improve" which also implies merit without examination.

The specification is objected to because 09/132118 has now issued as U.S. patent 6211337. The first line should be updated accordingly.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-3, 5, 6, 10-27, and 29-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The claims are drawn to polynucleotides comprising only small regions of the disclosed sequence. Such polynucleotides vary substantially in length and in composition, and could have very different structural and functional characteristics from the polynucleotides that encodes SEQ ID NO: 2. Applicant has not described any common characteristics linking these different polynucleotides so that the skilled artisan could identify them as members of a genus. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. Since the required region common region is only one amino acid, it is not sufficient to impart either characteristic physical, structural or functional features to the invention. The skilled artisan thus cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, regardless of the complexity or simplicity of the method of isolation. There is no way to tell what variants would have the characteristics of the genus. Claims 1, 3, 5, 6, 10-27, and 29-34 do not require any particular function that would serve to identify the molecules encompassed by the genus so that one of skill would recognize that Applicant was in possession of them. The functional limitations of claim 2 are also not sufficient to identify the encompassed molecules. The requirement that the encoded polypeptide either have a kinase activity, inhibit a kinase activity, or have or inhibit RIP binding activity is not sufficient to identify the claimed molecules; the claimed invention could phosphorylate any substrate, or inhibit the phosphorylation of any substrate. There is no common structure or distinguishing characteristic required for such a wide variety of activities.

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Similarly, "RIP binding" and inhibition of such binding does not require any particular characteristic. There is no requirement that the binding be to TRADD or TRAF2 or any other molecule whose interaction with RIP is characteristic of RIP. Thus the functional limitation of claim 2 is not sufficient to identify the claimed molecules, because it does not require any function that would be characteristic of the genus as a whole.

5. Claims 1-3, 5, 6, 10-27, and 29-34 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotides encoding SEQ ID NO:2, does not reasonably provide enablement for sequences comprising only fragments of the disclosed sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

As stated above, the claims are drawn to polynucleotides encoding sequences comprising fragments of the disclosed sequence. The claims are thus broad because they encompass polynucleotides very different from the disclosed sequence and because the claims have no meaningful functional limitation, as stated above. Applicant has shown that the polypeptide of SEQ ID NO: 2 is a kinase and binds TRADD and TRAF2. However, the specification does not

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provide guidance for using any encoded polypeptides that do not have these characteristic functions but are encompassed by the claims. The prior art does not provide compensatory teachings as to how one use such molecules; the proteins known in the art have similar functions and thus provide no guidance as to how one of skill might use molecules that did not have such functions. That a molecule is a kinase or kinase-related provides no guidance; kinases have many different functions.

For these reasons, which include the complexity and unpredictability of the nature of the invention and art in terms of the diversity of kinases, and lack of knowledge about function(s) of encompassed polynucleotides encoding polypeptides structurally related to SEQ ID NO: 2, the one working example of SEQ ID NO: 2, the lack of direction or guidance for using polypeptides that are not identical to at least the mature form of SEQ ID NO: 2, and the breadth of the claims for structure without function, it would require undue experimentation to use the invention commensurate in scope with the claims.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This claim is indefinite in the recitation of "RIP binding". It is not clear to what RIP is binding, or, alternatively, whether Applicant's invention is required to bind to RIP. One of skill in the art would not be able to determine what binding characteristics Applicant intended the molecule to possess, and thus what molecules Applicant intended the claims to encompass.

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Allowable Subject Matter

8. Claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

CLAIMS 1-3, 5, 6, 10-27, AND 29-34 ARE REJECTED. CLAIM 28 IS OBJECTED TO.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

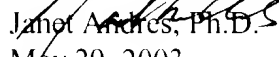
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to yvonne.eyler@uspto.gov.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Janet Andres, Ph.D.
May 29, 2003